OCT 3 0 2003

K033194

510(k) SUMMARY
For the Inion CPS™ Baby 1.5 Bioabsorbable Fixation System
September/25/2003

ADMINISTRATIVE INFORMATION

Manufacturer's Name: Inion Ltd.
Lääkärinkatu 2
FIN-33520 Tampere

Contact Person:
Hanna Marttila
Regulatory Affairs Manager
Phone: +358 3 230 6600
Fax: +358 3 230 6601

DEVICE NAME

Common/Usual Name: bone plating system
Classification Name: bone plates and screws

ESTABLISHMENT REGISTRATION NUMBER

9710629

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21 CFR 888.3040 bone fixation fasteners are classified as Class II.
Screws have been assigned Product Code HWC.

As shown in 21 CFR 872.4760 bone plates are classified as Class II.
Bone plates have been assigned Product Code 76 JEY

PREDICATE DEVICE

(1) Inion CPS™ Baby 1.5 Bioabsorbable Fixation System (K010351)

INTENDED USE

Indications for use remain identical with the previously cleared Inion CPS™ Baby Bioabsorbable Fixation System (K010351) and are as follows:

General indications: The Inion CPS™ Baby 1.5 Bioabsorbable Fixation System is intended for use in trauma and reconstructive procedures in the craniofacial skeleton, midface and maxilla.

Specific indications:

- Fractures of the cranium, midface and maxilla.
- Infant craniofacial surgery (i.e. craniosynostosis, congenital malformations).
- LeFort (I, II, III) osteotomies.
- Pediatric reconstructive procedures.
- Orthognathic or reconstructive procedures of the cranium, midface or maxilla.
- Craniotomy flap fixation.

Contraindications:

The Inion CPS Baby™ 1.5 Bioabsorbable Fixation System is not intended for use in and is contraindicated for:

1. Mandibular tumor resection.
2. Active or potential infection.
3. Patient conditions including limited blood supply, insufficient quantity or quality of bone; and where patient cooperation cannot be guaranteed. (e.g., alcoholism, drug abuse)
4. DO NOT USE in the mandible.

EQUIVALENCE TO MARKETED PRODUCTS

The Inion CPS™ Baby 1.5 Bioabsorbable Fixation System is identical to the previously cleared Inion CPS™ Baby 1.5 Bioabsorbable Fixation System (K010351). Devices itself have not been modified.

Based on 80 weeks data *in vitro* degradation data Inion has up to date, we believe, it is justified to claim implants to loose their strength over 9-16 weeks *in vivo* with complete strength loss and resorption **within one to two years.** This change does not raise any new questions on safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2003

Ms. Hanna Marttila
Regulatory Affairs Manager
Inion Limited
Lääkärinkatu 2
FIN-33520, Tampere
FINLAND

Re: K033194
Trade/Device Name: Inion CPS™ Baby 1.5 Bioabsorbable Fixation System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: September 25, 2003
Received: October 3, 2003

Dear Ms. Marttila:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594- 4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

D STATEMENT OF INDICATIONS FOR USE

Applicant: Inion Ltd.
510(k) Number:
Device Name: Inion CPS ™ Baby 1.5 Bioabsorbable Fixation System

Indications for Use:

Indications:

A. General indications: The Inion CPS™ Baby 1.5 Bioabsorbable Fixation System is intended for use in trauma and reconstructive procedures in the craniofacial skeleton, midface and maxilla.
B. Specific indications:
    - Fractures of the cranium, midface and maxilla.
    - Infant craniofacial surgery (i.e. craniosynostosis, congenital malformations).
    - LeFort (I, II, III) osteotomies.
    - Pediatric reconstructive procedures.
    - Orthognathic or reconstructive procedures of the cranium, midface or maxilla.
    - Craniotomy flap fixation.

Contraindications:

The Inion CPS Baby™ 1.5 Bioabsorbable Fixation System is not intended for use in and is contraindicated for:

1. Mandibular tumor resection.
2. Active or potential infection.
3. Patient conditions including limited blood supply, insufficient quantity or quality of bone; and where patient cooperation cannot be guaranteed. (e.g., alcoholism, drug abuse)
4. DO NOT USE in the mandible.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033A4